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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,272	11/22/2004	Domenico Maglione	10500-008	4002

29391 7590 05/20/2005

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EXAMINER

TSAY, MARSHA M

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/507,272	<b>Applicant(s)</b> MAGLIONE ET AL.	
	<b>Examiner</b> Marsha M. Tsay	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 16-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims 1-15 were cancelled in a preliminary amendment received on September 3, 2004. Claims 16-35 are pending and under examination.

Priority: The instant application was filed on November 22, 2004. This application is a 371 of PCT/IT03/00132, filed on March 5, 2003, which in turn claims foreign priority to IT RM2002000119, filed March 5, 2002. Therefore the priority date is March 5, 2002, in term of filing benefits.

### ***Claim Objections***

Claims 16, 23, 35 are objected to because of the following informalities: in claims 1 and 23, the term "ageing" should be changed to "aging"; in claim 35, the term "stabilising" should be changed to "stabilizing". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-26, 28-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 23-24 are drawn to a method of use of type 1 Placental Growth Factor (PLGF-1) comprising administering PLGF-1. The claims are indefinite because it is unclear to what or who the PLGF-1 is being administered to.

Claims 25-26, 28-29 are included in this rejection because they are dependent on claims 23-24.

Claims 30-31 are drawn to a pharmaceutical and cosmetic composition comprising PLGF-1, respectively. The claims should identify or spell-out that PLGF-1 is type 1 Placental Growth Factor.

Claims 32-33 are drawn to a W/O emulsion and a O/W emulsion. It is acknowledged that on page 10 of the instant specification, Applicants define W/O and O/W emulsion. However, an emulsion of water/oil or of oil/water will still create the same composition, therefore it is unclear what the distinction between a W/O emulsion versus a O/W emulsion is.

Claims 34-35 are included in this rejection because they are dependent on claims 30-31.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-22, 27, 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Ziche et al. (1997 Lab. Invest. 76(4): 517-531). Ziche et al. teach PIGF was assayed for angiogenic activity in the rabbit cornea and promotes angiogenesis in the avascular rabbit cornea (p. 518). In Figures 2A and 3, Ziche et al. demonstrate that after 7 days post-corneal implant of PIGF-1 at 20, 50, 100, and 200 ng/pellet, development of a network of new vessels was observed in 30%, 40%, 67%, and 100% of the implants, respectively (claim 16, 20-21). Furthermore, neoangiogenesis elicited by PIGF-1 observed in vivo increased with time (Fig. 2A; table 1; claim 16, 20-21). Claim 16 is drawn to a method of use of PLGF-1 comprising preparing a medicament that comprises PLGF-1 as an active principle. Claims 17-22, 27 are anticipated by Ziche et al. because they are also just methods of using PLGF-1 comprising preparing a medicament that comprises PLGF-1 as an active principle.

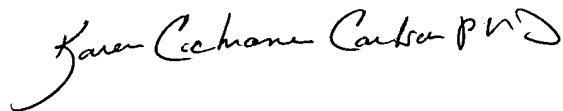
Ziche et al. teach PIGF-1 protein was purified mostly as homodimeric glycosylated protein and was approximately 0.17 mg/l of conditioned medium (p. 528; claim 30-35). Densitometric scanning of the stained gels revealed that 0.4%, 86.3%, and 13.2% of the total protein corresponded with monomeric, dimeric, and trimeric forms of PIGF-1, respectively (p. 518; claim 30-35). Claims 30-35 are drawn to a pharmaceutical composition comprising PLGF-1 protein, therefore regardless of the units of dosage recited by the claims, the Ziche et al. reference still meets the claim limitations in that it teaches a pharmaceutical composition comprising PLGF-1 in the appropriate monomeric, dimeric, and trimeric forms.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



May 13, 2005

**KAREN COCHRANE CARLSON, PH.D**  
**PRIMARY EXAMINER**